

### REMARKS

In the August 24, 2004 Office Action, the Examiner issued a Restriction Requirement that requires the Applicant to elect “a method of identifying and treating a specific disease or condition, such as one of those listed in Claims 10, 11, 21 or 22.” Office Action at page 2). Applicant provisionally elects allergic blepharoconjunctivitis with traverse. Claims 1, 3, 5-8, 17-19, 23-26, 29, 30, 33, 34, 37, 38 and 41 are generic.

A Restriction Requirement is proper when two criteria are satisfied: 1) the claimed inventions are independent or distinct as claimed; and 2) a search of the claimed subject matter would impose a serious burden on the Examiner. (MPEP § 803). Applicants respectfully submit that the Examiner did not provide a *prima facie* showing that a search and/or examination of the claimed subject matter would impose a serious burden. The Examiner has not demonstrated any of the several indicia of a serious search and examination burden. Specifically, the Examiner has not demonstrated that the allegedly different inventions would: 1) be classified separately; 2) have achieved a separate status in the art; or 3) require a different field of search as defined in MPEP § 802.02. (MPEP § 803).

The Examiner has provided no evidence or reasoning that would support a *prima facie* showing that a search and/or examination of the claimed invention would impose a serious burden. In the Office Action, however, the Examiner asserts that Applicant’s June 3, 2004 Amendment recites “newly claimed inventions” thereby necessitating a species requirement. (Office Action at page 2). The amended claims, however, neither add additional inventions as new claims nor transform the claims into inventions different than those originally filed on August 25, 1999 (claims 1-16) or added by preliminary amendment (claims 17-23) on May 14, 2001.

Applicant’s Amendment does not necessitate a Restriction Requirement for several reasons. First, species claims 21 and 22<sup>1</sup> have not been amended since they were first presented by preliminary amendment on May 14, 2001, and consequently, have already undergone multiple searches and examinations. Second, claims 1-23 are all

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<sup>1</sup> Claims 21 and 22 are specifically identified by the Examiner in paragraph 2A of the Office Action.

properly classified in class/subclass 424/282.1 and would not impose a serious search burden. Third, the Examiner has not demonstrated that the claims—as amended—would acquire a separate status in the art or a different field search from the numerous searches to which these claims have been subjected—factors that may be indicative of a serious search burden. Notably, claims 1-23 have been searched and examined by Exr. Ewoldt on at least four occasions—July 5, 2001; January 9, 2002; August 26, 2002; and September 25, 2003. Accordingly, the Examiner has merely concluded that a species election is necessary and has neither shown: 1) how the claim amendments transform the claims—claims that have been pending for over three (claims 17-23) and five years (claims 1-16) and that have been searched and examined by this Examiner on at least four occasions—into “newly claimed inventions”; or 2) how the amended claims impose a serious burden on the Examiner.

Even if the Examiner established a *prima facie* showing that the claimed subject matter is drawn to independent or distinct inventions, the Examiner should withdraw the Requirement, because the required “serious burden” for either a search or examination of the pending claims has not been established. The claims subject to the Examiner’s Requirement have already been extensively searched and examined, so any allegation of “serious burden” cannot stand. Consequently, since this necessary element of a Restriction Requirement has not been established, the MPEP states that “the Examiner must examine [the claimed invention] on its merits, even though it includes claims to independent or distinct inventions.” MPEP § 803. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding restriction requirement.

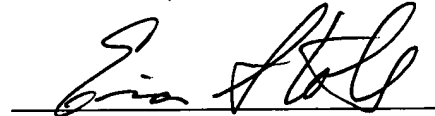
**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 13-3250, reference No. 02012.4121. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

If the Examiner finds that a telephone conference would further prosecution of this application, the Examiner is invited to contact the undersigned at 202-835-7512.

Respectfully submitted,

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